

### **REMARKS/ARGUMENTS**

Claims 46, 49-53, 81, 186, 194-199, 217-220, 246, 272-273 and 280-299 are pending. Claims 46, 53, 81, 186, 199, 271-220, 272, 286, 293 and 295-298 have been amended herein. Claims 50-52, 195-198, 280, 282-285 and 289-292 have been canceled. The Examiner has indicated that Claims 272 and 273 are allowed and has indicated that claims 53, 199, 281, 286-288, 293 and 294 are objected to as being dependent upon rejected claims 46 and 186, but would be allowable if rewritten in independent form. No new matter has been added by the amendments. Support for the amendments may be found throughout the specification and with respect to the recitation of 70% dephosphorylation, specifically in Example 2; and with respect to the further descriptions of phosvitin fragments, at page 6, lines 2-9 of the specification.

#### **Interview Summary:**

Applicant appreciates the courtesy extended to Applicant's representative on February 1, 2011, by Examiners Liu and Desai in conducting a telephone interview concerning this U.S. Patent Application. During the interview, proposed amendments to Claims 46 and 186 were discussed and agreement was reached as to the percent dephosphorylation that distinguishes over the cited references Reynolds and Jiang, as described in greater detail below.

#### **Claim Rejection Under 35 U.S.C. 112, first paragraph:**

The Examiner has rejected Claim 81 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically the Examiner asserts that the limitation of "A kit for contacting a cell, a tissue or an organ . . . comprising . . . a container holding a phosvitin or fragment thereof which at least 70% dephosphorylated", is not supported in the specification.

Applicants point out that "In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide **in haec verba** support for the claimed subject matter at issue." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (citing *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996)).

In this regard, support for a kit as claimed may be found on page 34, lines 8-18 of the specification as well as in Example 2. In addition, Claim 81 was previously amended to increase

the recited percentage of dephosphorylation from “at least 10%” to “at least 70%”, further limiting the claim which was not previously rejected under 35 U.S.C. 112, first paragraph. The term “at least 10%” encompasses the percentage of “at least 70%”. As there is support in the specification for this claim, Applicants respectfully request withdrawal of this rejection.

**Claim Rejections Under 35 U.S.C. § 103-Reynolds in view of Jiang:**

The Examiner has maintained the rejection of Claims 46, 49-52, 186, 194-198, 217, 219, 220, 246, 280, 282-285, 289-292, 295 and 297-299 under 35 U.S.C. § 103(a) as being obvious over Reynolds E.C. (U.S. Patent No. 6,780,844) (herein referred to “Reynolds”) in view of Jiang et al., *J. Agric. Food Chem.*, **48**:990-994 (2000) (herein referred to as “Jiang”). The Examiner bears the burden of establishing a *prima facie* case of obviousness to support a rejection of claims under 35 U.S.C. § 103(a). In determining obviousness, one must focus on the invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991). Accepted rationales for obviousness include a combination of prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; use of known technique to improve similar products in the same way; or applying a known technique to a known product ready for improvement to yield predictable results. *KSR v. Teleflex*, 550 U.S. 398, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007).

The Office action asserts that Reynolds teaches a complex containing phosphopeptide stabilized amorphous calcium fluoride phosphate and teaches a pharmaceutical composition comprising said complex, wherein the composition is a dental composition in a form of a gel, solid, powder or cream for treating dental caries or tooth decay wherein the dental cream is toothpaste; that the phosphopeptide is a casein protein fragment that is 20% dephosphorylated; that the phosphopeptide stabilizes the amorphous calcium phosphate (ACP); and that the stabilized ACP is most soluble wherein the stabilized and soluble ACP prevents caries and increases calcium bioavailability. The Office action does states that Reynolds **does not** expressly teach that the phospholipid is phosvitin or a fragment thereof nor teaches that the phosphopeptide is partially phosphorylated, e.g., 65% de-phosphorylated.

The Office action asserts that Jiang teaches that the partially phosphorylated (with 35%

phosphates retention) phosvitin phosphopeptide (PPP) inhibits calcium phosphate precipitation wherein 35% phosphate retention which is considered to be equivalent to about 65% dephosphorylation thereof shows the highest capability of solubilization of the insoluble calcium phosphates.

The Office action concludes that the combination of Reynolds and Jiang renders the claims obvious because although Reynolds uses the casein phosphopeptides (which are all 20% dephosphorylated), Reynolds suggests that the phosphopeptides can be obtained from any source that includes the known phosphor-acid rich proteins, phosvitin and because Jiang teaches that the phosvitin phosphopeptide (PPP) which is less than 65% dephosphorylated is superior to the casein phosphopeptide (CPP) in solubilizing calcium phosphate precipitation, this in turn would increase calcium bioavailability for pharmaceutical application.

Solely to expedite prosecution and without acquiescing in the rejection, Claims 46 and 186 have been amended so that the phosvitin or fragment thereof is at least 70% dephosphorylated. Neither Reynolds nor Jiang nor the combination of the two references teaches or suggests a composition that has 70% dephosphorylated phosvitin. In addition, neither reference provides any motivation for one of skill to increase the amount of dephosphorylation of either CPP or PPP as claimed.

Applicants submit that there is no suggestion or motivation in the references to make the pharmaceutical composition consisting essentially of a phosvitin or fragment thereof which is at least 70% dephosphorylated. Applicants therefore respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

**Claim Rejections Under 35 U.S.C. § 103-Reynolds in view of Jiang and Shuch:**

The Examiner has maintained the rejection of Claims 186, 194, 218 and 296, under 35 U.S.C. § 103(a) as being obvious over Reynolds E.C. (U.S. Patent No. 6,780,844) (herein referred to “Reynolds”) in view of Jiang et al., *J. Agric. Food Chem.*, **48**:990-994 (2000) (herein referred to as Jiang) and further in view of Shuch et al., (U.S. Patent No. 6, 503,483) (herein referred to as “Shuch”). The Office action uses the teachings of Reynolds and Jiang as above and further states that these references do not expressly teach that the formulated composition is in drop form. The Office action asserts that Shuch teaches that oral delivery system, i.e., formulation can be candy-gum “drops”.

Applicants maintain that the type of drops claimed in the present claims are not, and would not have been obvious in view of, candy-gum drops as taught by Shuch. Moreover, the teachings of Shuch do not make up for the deficiencies of Reynolds and Jiang as discussed above. Therefore, there is no suggestion or motivation in the references to make the combination, and Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,  
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